

# Bibliography

## 81-5 Primary dermal irritation

| MRID     | Citation Reference  |
|----------|---|
| 47915421 | Cantoreggi, S. (1998) Acute Dermal Irritation/Corrosion in the Rabbit: CGA 293343 WG 10, (A-11234 A): Final Report. Project Number: 982804. Unpublished study prepared by Novartis Animal Health US, Inc. 21 p. |

## 81-6 Dermal sensitization

| MRID     | Citation Reference  |
|----------|---|
| 47915422 | Cantoreggi, S. (1998) Skin Sensitization in the Guinea Pig (Buehler Test): CGA 293343 WG 10, (A-11234 A): Final Report. Project Number: 982806. Unpublished study prepared by Novartis Animal Health US, Inc. 31 p. |

## 810.3500 Premises treatments

| MRID     | Citation Reference   |
|----------|--|
| 47915201 | Whaley, S. (2009) Agita 1GB Fly Bait: Overall Summary of Product Performance Data: (Musca domestica). Unpublished study prepared by Novartis Animal Health US, Inc. 6 p.   |
| 47915202 | Kristensen, M. ; Jespersen, J. (2001) Speed of Action of Thiamethoxam and Azamethiphos in the Housefly Musca domestica. Project Number: 2/2000/VER/2. Unpublished study prepared by Danish Pest Infestation Laboratory. 13 p.  |
| 47915204 | Gfeller, F.; Moyses, E. (2000) Comparison of 1 GB Formulation of Thiamethoxam, Azamethiphos and Methomyl in a Laboratory Bioassay with Musca domestica. Project Number: IDL/632. Unpublished study prepared by Novartis Animal Health US, Inc. 26 p.   |
| 47915205 | Gfeller, F. (2001) Palatability, Attractiveness and Efficacy Laboratory Tests in M. domestica Using a New AGITA Granular Formulation (Placebo - Batch 709/2001). Project Number: LP/644, IDL681. Unpublished study prepared by Novartis Animal Health US, Inc. 30 p.   |
| 47915206 | Geissler, A.; Hyman, W.; Ludick, L. (2003) A Placebo-Controlled Field Study to Confirmed Insecticide Efficacy in Fly Control of a Scatter Bait Containing Thiamethoxam (CGA 293343 1GB) in Poultry Houses. Project Number: AGIGBRSA/102. Unpublished study prepared by Novartis Animal Health US, Inc. 82 p. |
| 47915207 | Kristensen, M.; Knorr, M.; Jespersen, J. (2002) Susceptibility to Thiamethoxam in Danish Field Populations of Houseflies (Musca domestica). Project Number: 01/2001. Unpublished study prepared by Danish Pest Infestation Laboratory. 32 p.   |
| 47915401 | Whaley, S. (2009) Agita 10 WG: Overall Summary of Product Performance Data. Unpublished study prepared by Novartis Animal Health US, Inc. 7 p.   |
| 47915402 | Moyes, E. ; Gfeller, F. (1994) CGA 293343: Topical and Oral Activity Against Musca domestica and Blattella germanica. Project Number: 449. Unpublished study prepared by CIBA-GEIGY Limited. 29 p.   |

47915403 Moyses, E. ; Gfeller, F. (1997) CGA 293343: Comparison of Formulation Variants with Commercial Standards in Local Field Tests Against Flies. Project Number: 560. Unpublished study prepared by CIBA-GEIGY Limited. 30 p.

47915404 Moyses, E. ; Gfeller, F. (1997) CGA 293343 WG 10: Efficacy as a Paint-On Bait in a Room Against Musca domestica (Standard: Alfacron Plus). Project Number: 562. Unpublished study prepared by CIBA-GEIGY Limited. 21 p.

47915405 Heng, Y. (1998) Field Efficacy of MF 1846 (WG 10) and Alfacron (WP 10) against house fly (Musca domestica). Unpublished study prepared by Universiti Sains Malaysia. 15 p.

47915406 Knorr, M. ; Kristensen, M. ; Jespersen, J. (2001) Efficacy of Agita 10WG against the Housefly Musca domestica When Applied under Field Conditions as Paint-On Bait. Project Number: 08/2001. Unpublished study prepared by Danish Pest Infestation Laboratory. 42 p.

47915407 Rossgger, W. (2002) Use of Thiamethoxam and Azamethiphos to Control Alphetobius diaperinus (Coleoptera, Tenebrionidae) in Broiler Farms. Unpublished study prepared by Sao Paulo State University. 15 p.

47915408 Greyling, D. (2004) The Use of Two Pyrethroids and A Neonicotinoid Based Agents for the Control of Alphetobius diaperinus in Poultry Houses. Prepared by Tech Vet Laboratory. 63 p.

47915409 Knorr, M.; Kristensen, M. ; Skovgard, H. ; et al. (2006) Field Evaluation of Agita 10WG Compared to QuickBayt 10WG When Applied as Paint-On Bait for Control of the Housefly Musca domestica. Project Number: 03/2006. Unpublished study prepared by Danish Pest Infestation Laboratory. 24 p.

47915410 Monteys, V.; Vidal, J. (2007) Efficacy of Agita and QuickBayt Adulticides for Controlling Summer Populations of the House Fly (Musca domestica) in a Commercial Pig Farm in Catalonia (Spain). Unpublished study prepared by Barcelona University. 72 p.

**830.1550      Product Identity and composition**

| MRID     | Citation Reference  |
|----------|---|
| 47915208 | Whaley, S. (2009) Agita 1GB Fly Bait: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 64 p. |
| 47915411 | Whaley, S. (2009) Agita 10 WG: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 70 p.        |

**830.1600      Description of materials used to produce the product**

| MRID     | Citation Reference  |
|----------|---|
| 47915208 | Whaley, S. (2009) Agita 1GB Fly Bait: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 64 p. |
| 47915411 | Whaley, S. (2009) Agita 10 WG: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 70 p.        |

**830.1650      Description of formulation process**

| MRID | Citation Reference |
|------|--------------------|
|------|--------------------|

47915208 Whaley, S. (2009) Agita 1GB Fly Bait: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 64 p.

47915411 Whaley, S. (2009) Agita 10 WG: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 70 p.

830.1670 Discussion of formation of impurities

| MRID     | Citation Reference  |
|----------|---|
| 47915208 | Whaley, S. (2009) Agita 1GB Fly Bait: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 64 p. |
| 47915411 | Whaley, S. (2009) Agita 10 WG: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 70 p.        |

830.1750 Certified limits

| MRID     | Citation Reference  |
|----------|---|
| 47915208 | Whaley, S. (2009) Agita 1GB Fly Bait: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 64 p. |
| 47915411 | Whaley, S. (2009) Agita 10 WG: Product Identity and Composition. Unpublished study prepared by Novartis Animal Health US, Inc. 70 p.        |

830.1800 Enforcement analytical method

| MRID     | Citation Reference  |
|----------|---|
| 47915209 | Suri, B. (2001) Analytical Method BE-258.H.3 for CGA 293343 and (Z)-9-Tricosene in Agita 1GB Fly Bait Formulation A-12339 A. Project Number: BE/258/H/3. Unpublished study prepared by Novartis Animal Health, Inc. 41 p. |
| 47915412 | Suri, B. (1998) Analytical Method BE-238/1 for CGA 293343 and (Z)-9-Tricosene in Agita 10 WG Formulation A-11234 A. Project Number: BE/238/1. Unpublished study prepared by Novartis Animal Health US, Inc. 13 p.         |

830.6302 Color

| MRID     | Citation Reference  |
|----------|---|
| 47915413 | Edinburge, G. (2000) Specific for Registration Edition 1: Valid form 01-MAR-00 A11234A Agita CGA293343 (10). Unpublished study prepared by Novartis Animal Health US, Inc. 4 p. |

830.6303 Physical state

| MRID     | Citation Reference  |
|----------|---|
| 47915413 | Edinburge, G. (2000) Specific for Registration Edition 1: Valid form 01-MAR-00 A11234A Agita CGA293343 (10). Unpublished study prepared by Novartis Animal Health US, Inc. 4 p. |

830.6314      Oxidizing or reducing action

| MRID     | Citation Reference   |
|----------|--|
| 47915210 | Angly, H. (2000) Test Report 2000.4014.OXP Oxidizing Properties of Solids: (Thiametoxam 1% GB1). Project Number: SIDATGBQ/03032000. Unpublished study prepared by Institute of Safety & Security. 7 p. |
| 47915414 | Angly, H. (1998) Test Report 98.4055.0XP Oxidizing Properties of Solids. Unpublished study prepared by Institute of Safety & Security. 7 p.  |
| 48773101 | Liu, Y. (2012) Agita 10 WG: Product Chemistry: (Group B): Final Report. Project Number: 15836/11. Unpublished study prepared by Stillmeadow, Inc. 8p.  |

830.6315      Flammability

| MRID     | Citation Reference   |
|----------|--|
| 47915211 | Angly, H. (2000) Test Report 2000.4014.FLS Flammability of Solids: (Thiametoxam 1% GB1). Project Number: SIDATGB1/03032000. Unpublished study prepared by Institute of Safety & Security. 7 p. |
| 47915415 | Angly, H. (1998) Test Report 98.4055.FLS Flammability of Solids. Unpublished study prepared by Institute of Safety & Security. 7 p.  |

830.6316      Explodability

| MRID     | Citation Reference   |
|----------|--|
| 47915212 | Angly, H. (2000) Test Report 2000.4014.EXP Explosive Properties: (Thiametoxam 1% GB1). Project Number: SIDATGB1/03032000. Unpublished study prepared by Institute of Safety & Security. 9 p. |

830.6317      Storage stability

| MRID     | Citation Reference   |
|----------|--|
| 47915213 | Blom, N. (2003) Shelf Life and Storage Recommendation AGITA 1GB, A-12339 A. Project Number: HPE/057, HPE/058, HPE//059. Unpublished study prepared by Novartis Animal Health US, Inc. 28 p.  |
| 47915416 | Blom, N. (2007) Shelf Life and Storage Recommendations Agita 10 WG A-11234 A. Project Number: HPE/051, HPE/052, HPE/062. Unpublished study prepared by Novartis Animal Health US, Inc. 36 p. |

830.6320      Corrosion characteristics

| MRID     | Citation Reference   |
|----------|--|
| 47915213 | Blom, N. (2003) Shelf Life and Storage Recommendation AGITA 1GB, A-12339 A. Project Number: HPE/057, HPE/058, HPE//059. Unpublished study prepared by Novartis Animal Health US, Inc. 28 p.  |
| 47915416 | Blom, N. (2007) Shelf Life and Storage Recommendations Agita 10 WG A-11234 A. Project Number: HPE/051, HPE/052, HPE/062. Unpublished study prepared by Novartis Animal Health US, Inc. 36 p. |

**830.7000      pH**

| MRID     | Citation Reference  |
|----------|---|
| 47915413 | Edinburge, G. (2000) Specific for Registration Edition 1: Valid form 01-MAR-00 A11234A Agita CGA293343 (10). Unpublished study prepared by Novartis Animal Health US, Inc. 4 p. |

**830.7300      Density/relative density**

| MRID     | Citation Reference   |
|----------|--|
| 47915417 | Patel, A. (2006) Bulk Density of Agita 10 WG A-11234-A. Project Number: 5747. Unpublished study prepared by Jai Research Foundation. 25 p. |

**830.7520      Particle size, fiber length, and diameter distribution**

| MRID     | Citation Reference   |
|----------|--|
| 47915424 | Patel, A. (2006) Particle Size Distribution of Agita 10 WG A-11234-A. Project Number: 5746. Unpublished study prepared by Jai Research Foundation. 33 p. |

**870.1100      Acute oral toxicity**

| MRID     | Citation Reference   |
|----------|--|
| 47915214 | Whaley, S. (2009) Waiver Request not to Perform Acute Oral (in Rats), Acute Dermal (in Rats), Primary Eye (in Rabbits), Primary Dermal (in Rabbits), and Dermal Sensitization (in Guinea Pigs) Testing on Agita 1GB Fly Bait. Unpublished study prepared by Novartis Animal Health US, Inc. 8 p. |
| 47915418 | Cantoreggi, S. (1998) Acute Oral Toxicity in the Rat (Limit Test): CGA 293343 WG 10, (A-11234 A): Final Report. Project Number: 982802. Unpublished study prepared by Novartis Animal Health US, Inc. 20 p.  |

**870.1200      Acute dermal toxicity**

| MRID | Citation Reference |
|------|--------------------|
|------|--------------------|

47915214 Whaley, S. (2009) Waiver Request not to Perform Acute Oral (in Rats), Acute Dermal (in Rats), Primary Eye (in Rabbits), Primary Dermal (in Rabbits), and Dermal Sensitization (in Guinea Pigs) Testing on Agita 1GB Fly Bait. Unpublished study prepared by Novartis Animal Health US, Inc. 8 p.

47915419 Cantoreggi, S. (1998) Acute Dermal Toxicity in the Rat (Limit Test): CGA 293343 WG 10, (A-11234 A): Final Report. Project Number: 982803. Unpublished study prepared by Novartis Animal Health US, Inc. 22 p.

**870.1300      Acute inhalation toxicity**

| MRID     | Citation Reference  |
|----------|---|
| 47915215 | Whaley, S. (2009) Waiver Request not to Perform Acute Inhalation Toxicity (in Rats) Testing on Agita 1GB Fly Bait. Unpublished study prepared by Novartis Animal Health US, Inc. 8 p. |
| 47915423 | Whaley, S. (2009) Waiver Request not to Perform Acute Inhalation Toxicity Testing on Agita 10 WG. Unpublished study prepared by Novartis Animal Health US, Inc. 6 p.                  |

**870.2400      Acute eye irritation**

| MRID     | Citation Reference   |
|----------|--|
| 47915214 | Whaley, S. (2009) Waiver Request not to Perform Acute Oral (in Rats), Acute Dermal (in Rats), Primary Eye (in Rabbits), Primary Dermal (in Rabbits), and Dermal Sensitization (in Guinea Pigs) Testing on Agita 1GB Fly Bait. Unpublished study prepared by Novartis Animal Health US, Inc. 8 p. |
| 47915420 | Cantoreggi, S. (1998) Acute Eye Irritation/Corrosion in the Rabbit: CGA 293343 WG 10, (A-11234 A): Final Report. Project Number: 982805. Unpublished study prepared by Novartis Animal Health US, Inc. 19 p.   |

**870.2500      Acute dermal irritation**

| MRID     | Citation Reference   |
|----------|--|
| 47915214 | Whaley, S. (2009) Waiver Request not to Perform Acute Oral (in Rats), Acute Dermal (in Rats), Primary Eye (in Rabbits), Primary Dermal (in Rabbits), and Dermal Sensitization (in Guinea Pigs) Testing on Agita 1GB Fly Bait. Unpublished study prepared by Novartis Animal Health US, Inc. 8 p. |

**870.2600      Skin sensitization**

| MRID     | Citation Reference   |
|----------|--|
| 47915214 | Whaley, S. (2009) Waiver Request not to Perform Acute Oral (in Rats), Acute Dermal (in Rats), Primary Eye (in Rabbits), Primary Dermal (in Rabbits), and Dermal Sensitization (in Guinea Pigs) Testing on Agita 1GB Fly Bait. Unpublished study prepared by Novartis Animal Health US, Inc. 8 p. |

**Non-Guideline Study**

| MRID     | Citation Reference  |
|----------|---|
| 47915200 | Novartis Animal Health US, Inc. (2009) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Agita 1GB Fly Bait. Transmittal of 17 Studies.               |
| 47915216 | Patel, A. (2006) Particle Size Distribution of Agita 1GB A-12339-A. Project Number: 5745. Unpublished study prepared by Jai Research Foundation. 34 p.  |
| 47915217 | Fieseler, A. (2008) Determination of the Attrition Resistance of Agita 1GB. Project Number: 43521205. Unpublished study prepared by IBACON GmbH. 16 p.  |
| 47915400 | Novartis Animal Health US, Inc. (2009) Submission of Efficacy, Product Chemistry and Toxicity Data in Support of the Application for Registration for Agita 10 WG. Transmittal of 25 Studies.                     |
| 47915425 | Fieseler, A. (2008) Determination of the Attrition Resistance of Agita 10 WG. Project Number: 43002205. Unpublished study prepared by Institut fuer Biologische Analytik und Consulting IBACON. 16 p.             |
| 48229900 | Novartis Health US, Inc. (2010) Submission of Product Chemistry Data in Support of the Application for Registration of Agita 10 WG. Transmittal of 1 Study.   |
| 48229901 | Meeker, J. (2010) Agita 10 WG: Rationale Supporting Determination the Proposed Litter Beetle Use Pattern Should be Considered a Nonfood Use. Unpublished study prepared by Novartis Animal Health US, Inc. 107 p. |
| 48286900 | Novartus Animal Health US, Inc. (2010) Submission of Exposure and Risk Data in Support of the Applications for Registration of Agita 1 GB and Agita 10 WG. Transmittal of 1 Study.                                |
| 48286901 | Meeker, J. (2010) Agita 1 GB and Agita 10 WG: Response to Occupational and Residential Exposure Assessment Queries. Unpublished study prepared by Novartis Animal Health US, Inc. 137 p.                          |
| 48773000 | Novartis Animal Health US, Inc. (2012) Submission of Product Chemistry Data in Support of the Registration of Agita 1GB Fly Bait. Transmittal of 1 Study.   |
| 48773001 | Liu, Y. (2012) Agita 1 GB: Product Chemistry: (Group B). Project Number: 15837/11. Unpublished study prepared by Stillmeadow, Inc. 8p.  |
| 48773100 | Novartis Animal Health US, Inc. (2012) Submission of Product Chemistry Data in Support of the Registration of Agita 10 WG. Transmittal of 1 Study.  |